Page No.: W -

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

1	Visit Code	Date	Subject Initials	Subject Scree	n#:	Study#	
	Subject Qualification	67/21/03 mm dd yy	D/A/B F M L	Permanent#:	39	03-122085-106	
Gender:	☑ Male	☐ Female .		A	ge:	43 Years	
Does the su	ibject have any of	the following at the	treatment sites?				
L DERM	IATOLOGIC DIS	ORDER			No	Yes	Don't Know
1.	Psoriasis ?					·	·
2.	Eczema ?						
3.	Skin Cancer ?				/		
4.	Skin Allergies? Pl	ease specify:			V		
5.	Hives ?				/		
Does the S	ubject have any of	the following (pres	ent and past)?				
п. отн	ER MEDICAL IN	FORMATION			No	Yes	Don't Know
1.	Allergies.? Please	specify.	·				
2.	Hepatitis?						
3.	Heart and Vascular	Disease?					
4.	Liver Disease ?						·
5.	Kidney Disease?						
6.	Tuberculosis?						
7.	Diabetes? Contr	olled? Diet[] O	ral[] Insulin[]		_		
8.		usago, tur					
9.	Auto-immune dise	ase (Lupus erythema	tosus, thyroiditis, Al	DS, etc.) ?	٧		
10.	Organ transplant?					1	
11.	Any other condition	n not listed? Please	e specify:			/	
Is the sub	ject taking any me	dication? If yes, pl	ease specify below:	•	_		
III. MEI	DICATION				No	Yes	Don't Know
1.	Antibiotics, oral o	r systemic ?					
2.	Cortisone, Steroid	s, ACTH, Anti-react	ion Drugs ?			-	
3.	Heart Medication	?					
4.	Insulin ?						
5.	Other? Bau	en Aspirin	250mg to	conwhen			
Commen	 V		· · · · · ·		fg br	eventativ	e .
Based on	the above medical h	uistory, the subject is	: ØQualifie	d or 🗆	Not qu	ualified for the	study.
		Toru E Ra		Date:	87 mm	12/10 dd	<u>3</u> yy

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-Page No.: <u>TV - 4</u>

			INCLUSION CRITERIA						
Ch	eck one		·						
YES	NO)	Subject:						
			1. Is 18 through 65 years?						
,			2. Has signed informed consent?						
			3. Is healthy as evidenced by responses on DCF 1?						
			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders ?						
/	5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?								
			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?						
			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?						
			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?						
/			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?						
			10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?						
			11. Is willing to comply with all study protocol requirements?						
			EXCLUSION CRITERIA						
C	heck one	.>.	,						
) YES	NO	N/A	Subject:						
1	<u></u>		1. Is currently participating in another clinical study at this or any other facility?						
	~		2. Has participated in any type of hand or arm wash study within the past 7 days?						
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?						
			4. Has artificial nails or nail tips?						
	/		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?						
			6. Has eczema or psoriasis on their hands or wrists?						
Female	Female	Male	7. Is currently pregnant? ☐ Yes ☐ No Of child-bearing potential: ☐ Yes ☐ No ☐ Surgically Sterile, year ☐ Post-menopausal, year ☐ If of child bearing potential - β-HCG Test Results: ☐ negative ☐ positive 8. Is currently lactating?						
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would preclude participation?						
<u> </u>	<u> </u>	1.	11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.						
		1	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?						
	d upon der	Ø Qu:	cation: Interviewer's Initials/Date:						
Investi	gator's Sig	nature:	ann R. Brad Date: 08/10/03 mm dd yy						

HTR Study No.: 03-122085-1 Page No.: 11 - 4

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07/30/03 mm dd yy	$\frac{\mathcal{D}/\mathcal{A}/\mathcal{B}}{F M L}$	Permanent#:39	03-122085-106

 I. Is skin on subject's hands a If no, please indicate co 	nd wrists still free of der			
II. Has subject used non-antib	pacterial soap and follow			
III. Has subject been ill since t	he last visit? □Yes (Cor	nplete below)	No No	
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	ete below) 🖽 No	
Based upon the above respon				
Reasons for disqualifica	ation:		***************************************	
TO BE C	OMPLETED IF SUBJ	ECT HAS AN II	NTERCURRENT I	LLNESS
Date of Onset:	Date Reported	•	Date Resolve	d:
Describe condition:				
Was reaction related to treatm Action Taken: □None □ C	•	Possibly related	•	Other (explain)
□ Medicat	ion taken (Complete belo	ow) DHospitalized	i ☐ Other (expla	in)
Additional Comments:				
	CON	COMITANT ME	EDICATION	
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm/dd/yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		1 1	1 1	•
		1 1	/ /	
		/ /	1 1	
Comments:				
· Interviewer's Signature: M	any m. Worth	lew I	Date: <u>07/</u>	30 103

HTR Study No.: 03-122085 Page No.: W 431

Data Collection Form 4

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen # 285	Study#	
07/30/03 mm dd yy	D/A/B F M L	Permanent #:	03-122085-106	

		BA	SELINE	**************************************	:
LEI	FT HAND DILU	TIONS	RIG	HT HAND DILU	TIONS
10-4	10 ⁻⁵	10 ⁻⁶	10-4	10-5	10-6
TNTC	206	20	TNTC	157	15
THTC	146	14	TNTC	67	12
CFU/mL\Sy	Counted by:	SP / 8/1/03	CFU/mL\.\Y	Counted by:	SP/8/1/02

LEFT HAND		•		RIGHT	HANI		
10-1	10-2	10-3	10-4	10 ⁻¹	10-2	10 ⁻³	
TUTC	THIC	TNTC	46	7111	TUTC	TNTC	Z
TUTC	THIC	TUTC	46	THIC	THIC	TMTC	7:
TMC				TUTC			
CFU/mL 4.6765	Cou	nted by : <u>5P</u>	18/1/03.	CFU/mL 3.44105	Counted t	oy: <u>SP</u>	/ 8/

LEFT HAND			W	ASH 11	77	RIGHT	HA
10 ⁻¹	10-2	10 ⁻³	10-4	10-1	10-2	10-3	
INT	THE 39	73	8	TNTC	INT	39	
TATE	TNP H	62	6	TNT	TNTC	45	
TNTC	3)P3 8	1-03		TNC		7	
CFU/mL 6.8 x104	Counte	ed by: R	<u> 18-1-03</u>	CFU/mL_4.3×104	_ Counted by	y: R	/

Calculations by: PS /8.1.03 Raw data reviewed by JNB /08.01.03

Calculations Verified by: JNB /08.01.03

*10-1 dilution is the sum of 1.0 mL spread across 3 plates.

Underlined values are used for calculation of CFU/mL

TNTC - Too Numerous To Count

Investigator's Signature:

One Bunk Date: 08 / 19 / 93 mm dd yy

Subject Initials	D. A.B _ Subject # 39	
	•	

Study No.

Page No.

ADVERSE EVENTS

·	•							
Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investigat Signature/i
Cellulatio .	7-31-03	8/13/03	N	2	2		44	Jenn
Entry Comment/Note + P	obable	Lave	石	tost	orga	resim.	e.y.	9. In
31-03 Swells	ver on	boo	ho	of 1	reall	her	ref o	8-21-
arper	rda	pu	sla	6	<i>y</i>			وم
13/03 took 50	Oma	tylen	<u></u>	4x .	on 7	13110	3	
13/03 Hands 4	fore	arm	<u>a (</u>	^	رين	\		
	Onset Date	End Date	SAE	Severity	Action	Outcome	Relation-	Investiga
Symptom / Event		-0	Y/N		Taken		ship	Signature.
Entry Commont/Nato:) Lee	Cubou		er a	ates	8/13/	030	
Bate Commentations :	and.	MAA	~	000	~ /		m	41
	orma	<i>////</i>	m	0	n M	rise		7 0 -
8/13/03 went to		onls 8	<u> </u>		u haz	MAN O	4100	Ded a
50000 H	20	1 a 00a		<u> </u>	y da .	on lov	100	n d
TOCIVIO -		·epso		/VO 1 /	~ Cary	- Clar	100	Ma
Symptom / Event	Onset Da	te End Date	SAE'	Severity	Action Taken	Outcome	Relation ship	Investig Signature
Entry Comment/Note:				,				
		•						
Note: Severity, Relation	nehin and	Outcome	- NALI	ST has	letermine	nd by nein	ologi ir	vacticata:
Note. Deventy, Relatit	Many and	Outcome	الاال	o i ne c	ierei i i ii i i	a by hill	cipai III	resugator.

Severity:

1=Mild

2=Moderate

3=Severe

Relationship:

1=Definite

2=Probable

3=Possible

4=Unrelate

Action Taken:

1=None

2=Rx Therapy

3=Discontinued Study

4=Other (s)

Outcome:

1=Resolved w/o sequelae

2=Resolved w/ sequelae 3=Ongoing (describe)

4=Death

DERMATOLOGY			HISTORY & PHYS	CAL		
MUE					DAT	7-31-0:
·· DAVID RO	ONE		IWI			
ADDRESS 1020 LOV	ELAND-MADI	ERA ROAD	APT 10 2	PHONEPO		(0)
	, 011 45140		-17) DATE OF BIRTH		AGE
hE ·			···		PAGE NO. TI	3 127/2857
CHIEF COMPLAINT	Shen en	Doctor			TAGENO, 1	422
HISTORY OF	2001	Dear.	Dure	<u>nèn</u>	7	
TO CONTIGUES				- Onse		٠.
			•		7-31-	03
			CV	as un	Huff To	b
				Hor	of Worls	5 Troples
MEDICATIONS					9	
ALLERGIES			٠.	•		*
MEDICAL HISTORY	D ANEMIA	,				
					<u> </u>	
D DABETES	. D HEART					
D PEPTIC ULCER	D UYER				ner gebruik e gagetieren gebruik en beschied	فندروها فلنفطط فلنا كالله مطاة كرجيسة مينينة عنها
D TUBERCULOSIS	D KIDNÈY	• •	•			annageria and gar to consideration of particle and the consideration of the consideration of the constant of t
D HYPERTENSION	CANCER					
O ASTHMATHAYFEY	ER D ARTHRITIS					
D HIVES/ECZEMA	O					
FAMILY HISTORY				. 0		
PHYSICAL EXAM		affly 1				Tun Just
INVESTIGATIONS DIAGNOSIS	Colla	D. Oct		•		
TREATMENTI PLANS			DV. CT	DULTUTY C	Daur na	
7 7.1	2		50	PHLEXIN CA O MG #20 X P 1 B.I.D	FOR 10 DA	YS.

HTR Study No.: 03-122085

Page No.: 11-434 FOLLOW-UP VISIT

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Follow-up Visit	08,04,03 mm dd yy	D_{fM}	Permanent #: 39	03-122085-106

Date Subject Entered the Study:	Follow-Up Vişit Date:
07,21,03	18,04,03
	0010110
mm dd yy	mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? YES NO If yes, complete below: Clinical Observations: (Include date of onset and descriptions/s New Left wareless on a second sec	everity/locations, etc.) hours of foreasm
Medical Consultant's Signature:	8, 4, 03
E-Juin Dros) M.O	mm dd yy

Page No. IV -

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	07 /15 /03 mm dd yy	J /- / H F M L	Permanent #:	03-122085-106

Gender: Male Female	Age: 43	Years	
Gender: Male Female.	Age	rears	
Does the subject have any of the following at the treatment sites?			
I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis?		•	
2. Eczema?	_		
3. Skin Cancer ?			
4. Skin Allergies? Please specify:	_	**************************************	
5. Hives ?			
Does the Subject have any of the following (present and past)?			
II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify.	-		
2. Hepatitis?			<u> </u>
3. Heart and Vascular Disease?	~		
4. Liver Disease ?			
5. Kidney Disease ?			
6. Tuberculosis?			
7. Diabetes? Controlled? Diet[] Oral[] Insulin[]			
8. Cancer?			
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)			
10. Organ transplant?			
11. Any other condition not listed? Please specify:			
Is the subject taking any medication? If yes, please specify below:			
III. MEDICATION	No	Yes	Don't
1. Antibiotics, oral or systemic?			Kilov
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?			
3. Heart Medication ?			
4. Insulin?			
5. Other?		1	
Comments:			
Based on the above medical history, the subject is:	Not qualify	ed for the	etudu
Designation of the second money, and subject in.			
Interviewer's Signature: Sum R. Harrie D.	ate: 07/	$\frac{15}{\text{dd}}$	<u> </u>

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: **IV** - **436**

Visit Code	Date	Subject Initials	Subject Screen #: 121	Study #	
Subject Qualification	07/15/03 mm dd yy	J/- /H	Permanent#: 40	03-122085-106	

INCLUSION CRITERIA							
Ch	neck one		·				
YES	N	<u>o</u>	Subject:				
			1. Is 18 through 65 years?				
			2. Has signed informed consent?				
	-		3. Is healthy as evidenced by responses on DCF 1?				
			4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?				
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?				
V			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?				
ســ			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?				
~			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, talcs and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?				
			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?				
)			10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?				
•			11. Is willing to comply with all study protocol requirements?				
			EXCLUSION CRITERIA				
C	Check one	24.2					
) YES	NO	N/A	Subject:				
	/		1. Is currently participating in another clinical study at this or any other facility?				
	<u></u>		2. Has participated in any type of hand or arm wash study within the past 7 days?				
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?				
			4. Has artificial nails or nail tips?				
			5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?				
			6. Has eczema or psoriasis on their hands or wrists?				
Female	Female	Male	7. Is currently pregnant? ☐ Yes ☐ No Of child-bearing potential: ☐ Yes ☐ No ☐ TUDE ☐ Surgically Sterile, year 1981 ☐ Post-menopausal, year ☐ If of child bearing potential - β-HCG Test Results: ☐ negative ☐ positive 8. Is currently lactating?				
	/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?				
			10. Has another medical condition which in the opinion of the Investigator would preclude participation?				
			11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.				
		<u> </u>	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?				
		Qua	S/ H = .C.2				
)[gator's Sig		Date: <u>08/10/03</u>				

HTR Study No.: 03-122085-106
Page No.: 11-437

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

2 12 21 COLUMN TO THE PROPERTY OF THE PROPERTY									
Visit Code	Date	Subject Initials	Subject Initials Subject Screen #:						
Test Period	07/23/03 mm dd yy	<u> </u>	Permanent#:	03-122085-106					

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Eyes No If no, please indicate condition:								
II. Has subject used non-antib If no, please explain:	-			es □No				
III. Has subject been ill since the	ne last visit? □Yes (Cor	nplete below)	P No					
IV. Has subject used any new o	oral or topical medication	n? □Yes (Comple	te below) 🖎					
Based upon the above respons	ses, the subject is: EQ u	alified 🗆 Not (Qualified to contin	ue on the study.				
Reasons for disqualifica	tion:							
	•							
TO BE C	OMPLETED IF SUBJ	ECT HAS AN I	TERCURRENT II	LNESS				
Date of Onset:	Date Reported		Date Resolve	d:				
Describe condition:			•					
Was reaction related to treatme	ent? [Not related] I	Possibly related	☐ Definitely related	☐ Other (explain)				
Action Taken: None C	ontinued on study	Withdrawn from	the study	nsulted physician				
☐ Medicati	on taken (Complete belo	ow) []Hospitalized	l 🛘 Other (explai	(n)				
Additional Comments:								
	CON	COMITANT ME	DICATION					
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm/dd/yy	Stop Date mm / dd / yy	Indication (Reason for Taking)				
		1 1	/ /					
		1 1	/ /					
Comments:								
Interviewer's Signature: Bo	the M. Can	antest I	Date: 07/2	3 / 03				

Interviewer's Signature: 0 14	m n	Date: 07/23/03	
· Interviewer's Signature: Betty	111. Conover	mm dd yy	
			-

HTR Study No.: 03-122085-106 Page No.: **W** 436

Data Collection Form 4

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#	
07/23/03 mm dd yy	J/-/H F. M L	Permanent #:	03-122085-106	

BASELINE							
LEFT HAND DILUTIONS				RIGI	HT HAND DILUTIO	ONS	
10-4	10-5	10-6		10-4	10-5	10-6	
TNTC	182	14_		TNTC	151	17	
TNTC	762	31-		TNTC	700	17	
CFU/mL2.0XI	Counted by:	JNB 107.2503		CFU/mL /.2×	O Counted by: J	NB/07.25:03	

LEFT HAND			W.	ASH 1		RIGHT HAND		
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10-2	10-3	10-4	
TNTC	TNTC	TNTC	38	TNTC	TNTC	111	+16	
TNTC	TNIC	TNTC	27	TNTC	TNTC	152	İq	
TNTC				TNTC				
CFU/mL 3.2×105	Count	ed by : JNB	,07·25·23	CFU/mL /. 3 × 10 5	Counted by	: JNB	/07-25-03	

LEFT HAND		WASH 11				RIGHT	HAND
10-1	10 ⁻²	10-3	10-4	10-1	10-2	10-3	10-4
TNTC	TNTC	156-	15	TNTC	TNTC	58	6
TNTC	TNTC	T31-	17	TNTC	TNTC	51	- 11
TNTC				TNTC			
CFU/mL 1-4×105	Counte	Counted by: JNB /07.25.03		CFU/mL 6,4 × 10 4	Counted by	BNT:	107.25.03

Unc	culations by:	<u>alb</u>	18·1.03	
Inv	estigator's Signature:	Date:	8 111 103	

Investigator's Signature: Date: 9 / 11 / 53 mm dd yy

Data Collection Form 6 FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

Page No.: IX - 439

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Follow-up Visit	07/28/03 mm dd yy	J /- / H F M L	Permanent#: 40	03-122085-106

Date Subject Entered the Study: 07, 15,03 mm dd yy	Follow-Up Visit Date: D7, 28, 03 mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection?	or raised itching bumps surrounded by erythema and/or edema
Clinical Observations: (Include date of onset and descriptions/s	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatmen	t procedure?
☐ YES NO If yes, complete below	
Comments:	
Medical Consultant's Signature:	7,28,03 mm dd yy

HTR Study No.: 03-122085-106
Page No.: 11 -440

Data Collection Form 1

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

	OZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZZ							
Visit Code	Date	Subject Initials	Subject Screen #:	Study#				
Subject Qualification	07/21/03 mm dd yy	$\frac{L}{F} \frac{I - I}{M} \frac{N}{L}$	Permanent #: 41	03-122085-106				

Gender: Male Female Does the subject have any of the following at the treatment sites?	Age: <u>55</u>		
Does the subject have any of the following at the treatment sites?		Years	
I. DERMATOLOGIC DISORDER	No	Yes	Don't Know
1. Psoriasis ?	1		
2. Eczema?	1/		
3. Skin Cancer ?	1/		
4. Skin Allergies ? Please specify:	V .	***************************************	
5. Hives?			
Does the Subject have any of the following (present and past)?			
II. OTHER MEDICAL INFORMATION	No	Yes	Don't Know
1. Allergies.? Please specify. Environmental		V	
2. Hepatitis?	1		
3. Heart and Vascular Disease?	1		
4. Liver Disease?			
5. Kidney Disease ?			
6. Tuberculosis?	V.		
7. Diabetes? Controlled? Diet[] Oral[] Insulin[]	V		1
8. Cancer?	V.		
9. Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?			
10. Organ transplant?	V		
11. Any other condition not listed? Please specify:		1	
Is the subject taking any medication? If yes, please specify below:			
III. MEDICATION	No	Yes	Don't Know
1. Antibiotics, oral or systemic?			1 22.0 (
2. Cortisone, Steroids, ACTH, Anti-reaction Drugs?			
3. Heart Medication ?			
4. Insulin?	V		
5. Other? Vivelle. 0.05 patch HRT			

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106 Page No.: <u>W - 44</u>

		Visit	Code	Date	Subject Initials	Subject Screen #:	Study#	
			ject Ication	07/21/03 mm dd yy	$\frac{L_{f-N}}{f-1}$	Permanent #: 4	03-122085-106	
				INC	CLUSION CRITERI	A	**************************************	
Che	k one							
ÆS_	<u> </u>	<u>o</u>	Subject:				 	
				through 65 years?				
<u> </u>	 			signed informed conser				
V	-			althy as evidenced by r			. 11 1 0	
<u> </u>	4					cuts, lesions, and other sk	· · · · · · · · · · · · · · · · · · ·	
<u> </u>	/					imately one (1) mm past t		
V				rering, and handwashin		os (liquids and/or bars) for ady ?	batning,	
V			7. Is w	illing to refrain from us	ing anti-dandruff shar	npoo during the entire stu	dy?	
/			liqui		dorant/antiperspirant	licated/antibacterial lotion products during the entire		
/				illing to refrain from us sician for an intercurrer		uring the entire study, unl	ess prescribed by a	
V,	`			illing to refrain from uses prescribed by a phys		ic antibiotic medication du ent illness?	aring the entire study,	
V			11. Is w	villing to comply with a	ll study protocol requ	irements?		
			·	EX	CLUSION CRITER	IA		
	eck on		Cubiant					
ES	NO	N/A	Subject:		another clinical stud	y at this or any other facil	ita ?	
	/	ļ	 			h study within the past 7 d	· · · · · · · · · · · · · · · · · · ·	
	-	 		s cuts, lesions, or other				
	\\/			s artificial nails or nail		I IIIIII OL VIII OL		
	\rightarrow	1				l/or perfume allergies ?		
	-/	<u>' </u>	<u> </u>	s eczema or psoriasis or				
male	Female	Male	7. Is o	currently pregnant?	Yes No Of chil	d-bearing potential: 1 Ye	pausal, year	
	/		8. Is c	currently lactating?				
	√		her		ant, an immunologic o	cal condition such as: dia disease such as AIDS (or I is ?		
	V	1		s another medical conceclude participation?	lition which in the opi	nion of the Investigator w	ould	
	V		wo	ounds, intravenous man	agement or other bed-	er age 3, or has responsibileridden related care roles.		of
	<u> </u>		12. Ha	s a known sensitivity to	isopropyl alcohol or	the ingredients in antibact	erial soaps ?	
Based	upon d	rmatolo		ion and the information ☐ Not Qualified	contained in Data Co	ollection Forms 1 and 2, the this study.		
Reason	as for d	squalific		-		er's Initials/Date: JN	B 107.21.0	<i>13</i>

Investigator's Signature:

YES

Female

an R. Bus

Date: 08/10

HTR Study No.: 03-122085-106
Page No.: X-443

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code Date		Subject Initials Subject Screen #: Study #					
Test Period	07 28 03 mm dd yy	£/-/N F M L	Permanent#:	03-122085-106			

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? □Yes □No If no, please indicate condition:						
II. Has subject used non-antib	pacterial soap and follow					
III. Has subject been ill since t	he last visit? Yes (Cor	nplete below)	₽ No			
IV. Has subject used any new	oral or topical medicatio	n? □Yes (Comple	ete below) 🗆 No			
Based upon the above respon Reasons for disqualifica	ises, the subject is: SQuation:			when the study. When returned on 1/30/03 gm		
то ве с	OMPLETED IF SUBJ	ECT HAS AN II	NTERCURRENT I	LLNESS		
Date of Onset: Describe condition:		· · · · · · · · · · · · · · · · · · ·	•			
	Continued on study	Withdrawn from	the study Co	in)		
	CON	COMITANT MI	EDICATION			
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm/dd/yy	Stop Date mm/dd/yy	Indication (Reason for Taking)		
		1 1	1 1			
		1 1	/ /			
		1 1	1 1			
Comments:						
		<u> </u>				
Interviewer's Signature: M	ery m. Ware	Ram I	Date: <u>07/</u> mm	28103 dd yy		

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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

	HATERCORRENT INDIALES? CONCOMITANT MEDICATION FORM							
Visit (Code	Date	Subject Initials	Subject Screen #: 185	Study #			
Te: Peri		07 /30/03 mm dd vy	1 / - / N F M L	Permanent #:	03-122085-106			

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? Eyes No If no, please indicate condition:								
II. Has subject used non-antib	pacterial soap and follow							
III. Has subject been ill since t	he last visit? □Yes (Cor	mplete below)	Ø No					
IV. Has subject used any new	oral or topical medication	n? □Yes (Comple	te below) LiNo					
Based upon the above respon	ses, the subject is: 🛱 Qu	alified Not	Qualified to conti	inue on the study.				
Reasons for disqualifica	ation:							
	·							
TO BE C	OMPLETED IF SUBJ	ECT HAS AN IT	NTERCURRENT :	ILLNESS				
Date of Onset:	Date of Onset: Date Reported: Date Resolved:							
Describe condition:			•					
Was reaction related to treatme	ent? []Not related [] I	Possibly related	☐ Definitely relate	ed Other (explain)				
Action Taken: DNone D	Continued on study \Box	Withdrawn from	the study 🛛 C	onsulted physician				
□ Medicati	ion taken (Complete belo	ow) []Hospitalized	i 🛘 Other (expl	lain)				
Additional Comments:								
	CON	COMITANT ME	EDICATION					
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm/dd/yy	Indication (Reason for Taking)				
		1 1	1 1					
		1 1	1 1					
·								
Comments:								
Interviewer's Signature: M	eng m. Wout	an I	Date: <u>07</u> /	30 / 03 dd yy				

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen#	Study #	
07/30/03 mm dd yy	<u>L / - / N</u> F. M L	Permanent #:	03-122085-106	

	BASELINE							
LEFT HAND DILUTIONS				RIGHT HAND DILUTIONS				
10⁴	10-5	10 ⁻⁶		10-4	10 ⁻⁵	10-6		
TWIC	165	19		THIC	158	18		
TMC	114	15		THTC	93	LA		
CFU/mL\.\\	Counted by:	SP / 8/1/03		CFU/mL \.8 x1	Counted by:	SP 1 8/1/03		

LEFT HAND		•	W	ASH 1		RIGHT HAND			
10-1	10 ⁻²	10 ⁻³	4 483	10-1	10-2	10-3	10⁴		
TUTE	THIC	48	4 460	TUTC	TUTC	28	10		
TNTC	TUR	SL	5	TUTC	TUTE	73	13		
TNIC				TUTC					
CFU/ml 5.0764	Coun	ted by : _ <i>S</i>	7 8/1/03	CFU/mL & OXIOY	_ Counted by	: SP	18/1/03.		

LEFT HAND			W.		RIGHT HAND			
10 ⁻¹	10 ⁻²	10-3	10-4	10 ⁻¹	10 ⁻²	10-3	10-4	
THIC	81	9	0	241	107	7	1	
THIC	87	5	0	189	391	6	0	
THIC				186				
CFU/mL 8.4 + 10	Count	ted by :S	8/8/103	CFU/mL 69 +10	S Counted by	v: <u>5P</u>	18/1/03.	

Calculations by: 18.1.03 Raw data reviewed by	y JNB / 08.01.03
Calculations Verified by: <u>£45</u> / 9-1-03	
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.	* LA = Lab Accident SP 8/1/03
Underlined values are used for calculation of CFU/mL	21 21 1/183
TNTC - Too Numerous To Count	

Investigator's Signature:	am R. Bush	Date:	<u>08</u> /	<u>/// /</u> dd	93 yy
	1/				

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

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Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Follow-up Visit	08/04/0	$\frac{3}{4}$ $\frac{2}{4}$ $\frac{1}{4}$ $\frac{1}{4}$ $\frac{1}{4}$	Permanent #: 4/	03-122085-106

Date Subject Entered the Study: 07:21:03 mm dd yy	Follow-Up Visit Date: <u>08,04,03</u> mm dd yy
Does the subject's hands have the presence of pimples, blisters, of that may be indicative of a skin infection? If yes, complete below:	
Clinical Observations: (Include date of onset and descriptions/se	everity/locations, etc.)
Comments:	
Has the subject had any health related issues since the treatment	t procedure?
TYES NO If yes, complete below Comments:	
Comments	
Medical Consultant's Signature:	B Date 8, 4,03 mm dd yy

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 279	Study#
Subject Qualification	57,21,03 mm dd yy	R/K/B F M L	Permanent#: 42	03-122085-106

	Agammenton	mm dd	уу	F	M	L		12			
		·									
Gender:	☐ Male	Female	٠.					Age:	<u>54</u>	Years	
oes the	subject have any of t	the following	at the tr	reatme	nt site	s?	· · · · · · · · · · · · · · · · · · ·				
I. DER	MATOLOGIC DIS	ORDER					***************************************	No		Yes	Don't Know
1.	Psoriasis ?								7	•	
2.	Eczema ?			***************************************	*************		·····				
3.	Skin Cancer ?										
4.	Skin Allergies? Ple	ease specify:				***********					
5.	Hives?			· · · · · · · · · · · · · · · · · · ·			·		-		
Does the	Subject have any of	the following	(presen	nt and	past)?				···		
II. OTE	IER MEDICAL IN	FORMATIO	N					No		Yes	Don't Know
1.	Allergies.? Please	specify.				•		<u></u>			
2.	Hepatitis ?										
3.	Heart and Vascular	Disease?									
4.	Liver Disease?										
5.	Kidney Disease?										
6.	Tuberculosis?				***********	·					
7.	Diabetes? Contro	olled? Diet [] Ora	d[]	Insulin	[]					
8.	Cancer ?				*****************				7		
9.	Auto-immune disea	ase (Lupus ery	themato	sus, thy	roiditi	s, AID	S, etc.) ?				
10.	Organ transplant?				**********				,		†
11.	Any other condition	n not listed?	Please s	specify:	:						
Is the su	bject taking any med	dication? If y	es, plea	se spec	ify be	low:	•				**, **********************************
III. ME	DICATION							No	,	Yes	Don't Know
1.	Antibiotics, oral or	systemic?		**************************************					•		
2.	Cortisone, Steroids	s, ACTH, Anti	-reaction	n Drugs	s ?		***************************************				
3.	Heart Medication	?			······						
4.	Insulin ?			,	····						
5.	Other ?					***************************************					
Comme	nts:					***************************************					
~~mm	MW,										
Based or	n the above medical hi	istory, the subj	ect is:		Øua	lified	or 🗆	Not au	ıalific	ed for the	study.
,	ver's Signature:	Fanon	5 11	VII	1/1	-A	/ Date	7	7, 6) / , C	3
			_للـــــــــــــــــــــــــــــــــــ		2011/	<u> </u>		******		<u> </u>	УУ

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: W-447

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Subject Qualification	57/21/03	RIKIB	Permanent #: 42	03-122085-106

			INCLUSION CRITERIA						
Ch	eck one		·						
YES	N	0	Subject:						
i		1. Is 18 through 65 years?							
<u></u>			2. Has signed informed consent?						
			3. Is healthy as evidenced by responses on DCF 1?						
4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?									
			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?						
			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?						
			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?						
			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?						
/	/		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?						
/	/		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?						
,			11. Is willing to comply with all study protocol requirements?						
			EXCLUSION CRITERIA						
	heck one	۸.	•						
YES	NO	N/A	Subject:						
			1. Is currently participating in another clinical study at this or any other facility?						
			2. Has participated in any type of hand or arm wash study within the past 7 days?						
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?						
······································			4. Has artificial nails or nail tips?						
		<u> </u>	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?						
			6. Has eczema or psoriasis on their hands or wrists?						
Female	Female	Male	Surgically Sterile, year 1907/4 □ Post-menopausal, year 1907 If of child bearing potential - β-HCG Test Results: □ negative □ positive						
			8. Is currently lactating?						
			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?						
10. Has another medical condition which in the opinion of the Investigator would preclude participation?									
11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.									
		1	12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?						
		Z Qu	74K -11 11/2						
Reas	ons for di	squalifi							
Investi	gator's Sig	nature:	Date: 08/10/03 mm dd yy						

HTR Study No.: 03-122085-106
Page No.: W-448

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study#
Test Period	07/30/03 mm dd yy	R/K/B F M L	Permanent #: 42	03-122085-106

I. Is skin on subject's hands and wrists still free of dermatoses, cuts, lesions, and other skin disorders? EYes No If no, please indicate condition:									
II. Has subject used non-antibacterial soap and followed the instructions in Appendix B? EYes If no, please explain:									
III. Has subject been ill since the last visit? DYes (Complete below) No									
IV. Has subject used any new oral or topical medication? The Subject used any new oral or topical medication?									
Based upon the above respons	Based upon the above responses, the subject is: - Qualified								
Reasons for disqualification	tion:								
	·								
TO BE COMPLETED IF SUBJECT HAS AN INTERCURRENT ILLNESS									
Date of Onset:	Date of Onset: Date Reported: Date Resolved:								
Describe condition:									
Was reaction related to treatme	ent? Not related I	Possibly related	☐ Definitely related	☐ Other (explain)					
Action Taken: None C	ontinued on study	Withdrawn from	the study	nsulted physician					
□ Medication	on taken (Complete belo	ow) []Hospitalized	i 🛘 Other (expla	in)					
Additional Comments:									
	CON	COMITANT ME	EDICATION						
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)					
		1 1	/ /						
		1 1	1 1						
Comments:									
Interviewer's Signature: Mary M. Woutham Date: 07 / 30 / 63 mm dd yy									

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07/30/03 mm dd yy	R/K/B	Permanent #:	03-122085-106

		I	BASELD	NE				
LEF	T HAND DILUT	IONS		RIGHT HAND DILUTIONS				
10-4	10-5	10 ⁻⁶		10-4	10-5	10-6		
1311 ESPO LA ** 14				THTC	169	24		
613 ESP	* LA **	200		TNTC	154	15		
	Counted by:_	SP/8/1/03		CFU/mL\?	Counted by:	SP / 8/1/03		
1.77	107 3P-38.1	. ο 3		<u> </u>	· · · · · · · · · · · · · · · · · · ·			

LEFT HAND		•	elilas W.	ASH 1	RIGHT HAND		
10-1	10-2	10%	10-4	10-1	10 ⁻²	10-3	10-4
TUTC	THIC	-59 59	_3	TUTC	THIC	372	7
THIC	THIC	56	C	THE	TUTC	64	7
TUTC				THIC		<u> </u>	
CFU/mL 5.84104	Coun	ated by : 5P	18/1/03	CFU/mL6.07/04	Counted by	: SP	18/1/03.

LEFT HAND			W/	ASH 11		RIGHT HAND			
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	€ 10 ⁻²	10-3	10-4		
TNTC	108	10		TUTC	237	18	3		
TNTC	1510	21		TNE	263	29	4		
TMC	į			THE					
CFU/mL 1.3 x 104	_ Counted	d by : <u>₿</u>	1 8-1-Q3	CFU/mL 2.4 x 104	Counted by :	: P2	1 8-1-03		

Calculations by: PS /8.1.53 Raw data reviewed by _Calculations Verified by: / 6.1.53 Raw data reviewed by _ *10-1 dilution is the sum of 1.0 mL spread across 3 plates. Underlined values are used for calculation of CFU/mL TNTC - Too Numerous To Count	## LA = LATS Accopent 8/1/03 Continuination other the ESPC = Estimated Standard Plak Country SP 8/5/63
Investigator's Signature:	Date: 9 /14 /03 mm dd yy

	\wedge	, ,			onection form 5A		
Subject Initials	R	<u>K</u>	<u>B</u>	Subject#	42	Study No.	03-122085-106
						Page No.	II- 456
				, DYTTING	77 777 × ****		

ADVERSE EVENTS

	, ————————————————————————————————————		7.7				~		
Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	Investi Signatu	
Mergles	8-4-03	8/8/03	N	1	1	i	44	Q 14	8-211-1 m
Entry Date Comment/Note: Y	whatb	- deso	大	101	onso	nism:	9-9		hitials
8-4-03 ans.	sed)	won	est	o on	1 Still	A.	2. de F	821	03
uesi	10		7		1 - 2 - 4		J. Co		Dy A
3/8/ 1/1:1	Oan 1	<i>aa</i> n		- 4 4	rteón		/	, –	26
1709 WHUST C	Mar	mo,	/ YYZ.	WICI	ucon		sec		gr
							•		
Symptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship		tigator ıre/Date
Entry Date Comment/Note:			h						Initials

			·····						
					-				
Symptom / Event	Onset Date	End Date	SAE Y/N		Action Taken	Outcome	Relation-		tigator ure/Date
Entry Date Comment/Note:									Initials
									·
		•							
			·	•			•		1
Note: Severity, Relatio	nship and	Outcome	ML	JST be d	letermine	d by prin	cipal inv	estigato	or.

Severity:

1=Mild

2=Moderate

3=Severe

Relationship:

1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken:

1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome:

1=Resolved w/o sequelae

2=Resolved w/ sequelae 3=Ongoing (describe)

4=Death

¹Serious Adverse Event/Experience

FOLLOW-UP VISIT

HTR Study No.: 03-122085-106

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	Visit Code		Date		Subject Initials			Subject Screen #:	Study #
-	Follow-up Visit	0810 mm	<u>04</u> dd	03 yy	$\frac{\mathcal{R}}{F}$	KM	1 <u>B</u>	Permanent#: 42	03-122085-106

Date Subject Entered the Study: <u>07 21 03</u> mm dd yy	Follow-Up Visit Date; OB 1 04 1 03 mm dd yy
Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? YES INO If yes, complete below:	or raised itching bumps surrounded by erythema and/or edema
Clinical Observations: (Include date of onset and descriptions/s ONE NEW WORLD ON ONSET 8-4-03	severity/locations, etc.) right with
Comments:	·
Has the subject had any health related issues since the treatmen YES NO If yes, complete below	at procedure?
Comments:	
Medical Consultant's Signature:	Date 8, 4,03

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	Subject Screen #: 130	Study#
Subject Qualification	07/15/03 mm dd yy	JILIC. FML	Permanent #: 43	03-122085-106

L DERI	MATOLOGIC DISORDER	No	Yes	Don't Know
1.	Psoriasis ?			
2.	Eczema?	V		
3.	Skin Cancer?	V.		
4.	Skin Allergies ? Please specify:	V		
5.	Hives ?	V		
Does the	Subject have any of the following (present and past)?			
п. отн	ER MEDICAL INFORMATION	No	Yes	Don't Know
1.	Allergies.? Please specify.	V/	•	
2.	Hepatitis ?	V /		
3.	Heart and Vascular Disease?	//		
4.	Liver Disease ?	1		
5.	Kidney Disease ?	V/		
6.	Tuberculosis?	//		
7.	Diabetes? Controlled? Diet[] Oral[] Insulin[]	V		
8.	Cancer? Cancer (breast) in remission since 1986 07.19	.03	V	
9.	Auto-immune disease (Lupus erythematosus, thyroiditis, AIDS, etc.)?	V,		
10.	Organ transplant ?			
11.	Any other condition not listed? Please specify: See below **		. /	
Is the su	bject taking any medication? If yes, please specify below:			
m. Me	DICATION	No	Yes	Don't Know
1.	Antibiotics, oral or systemic?	V.	•	
2.	Cortisone, Steroids, ACTH, Anti-reaction Drugs?	//		
3.	Heart Medication ?			
4.	Insulin ?	V	/	
5.	Other? Brista 60mg 1x day osteoporosis prevention **		V	
Comme	nts: Calcium + Vitamins LXday	449444 a 440 a 260 a		e de la companya de l
Based on	the above medical history, the subject is:	Not qualifie	d for the s	tudy.
	! •	_ · .	5. D:	~ ·

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-106
Page No.: 11 - 453

1		y			
	Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	Subject Qualification	07/15/03	JILIC	Permanent #: 43	03-122085-106

INCLUSION CRITERIA								
	neck one	^						
YES	No.		Subject:					
V_{ℓ}	<u>/</u>		1. Is 18 through 65 years?					
_V,	4		2. Has signed informed consent?					
V,	4		3. Is healthy as evidenced by responses on DCF 1?					
	4		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?					
<u> </u>	/		5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?					
✓			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?					
V			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?					
ν			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?					
V			9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?					
V	· /		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?					
V			11. Is willing to comply with all study protocol requirements?					
			EXCLUSION CRITERIA					
0	Check one		`					
YES	NO /	N/A	Subject:					
			Is currently participating in another clinical study at this or any other facility?					
	V	/	2. Has participated in any type of hand or arm wash study within the past 7 days?					
			3. Has cuts, lesions, or other skin disorders on their hands or wrists?					
	V		4. Has artificial nails or nail tips?					
	V	,	5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?					
	1		6. Has eczema or psoriasis on their hands or wrists?					
Female	Female	Male	7. Is currently pregnant? The Wood of child-bearing potential: Yes Wood No Surgically Sterile, year Post-menopausal, year 444 1995 If of child bearing potential - β-HCG Test Results: negative positive TNB 07.15.03 8. Is currently lactating?					
	\/ \/		9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis? 10. Has another medical condition which in the opinion of the Investigator would preclude participation?					
11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care wounds, intravenous management or other bed-ridden related care roles.								
	1,/		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?					
		'						
Based		matolog M Qua						
Reas	ons for dis	qualific	ation: Interviewer's Initials/Date: JNB ,07.15.0.3					
Investig	Investigator's Signature: One R. Brack Date: O8 , 10 , 03 / mm dd yy							

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Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

_		· AMATOUATE AM	DZ (DDD)	CARTILL MANDACIATA	TI T OTTIT
	Visit Code	Date	Subject Initials	Subject Screen #:	Study #
	Test Period	07 /23 / 03 mm dd yy	J/L/C F M L	Permanent#: 43	03-122085-106

I. Is skin on subject's hands and If no, please indicate cond		•	•	lisorders? Des ONo
II. Has subject used non-antiba If no, please explain:				es 🗆 No
III. Has subject been ill since the	e last visit? 🗆 Yes (Con	nplete below) [₹ No	
IV. Has subject used any new or	al or topical medication	n? □Yes (Comple	te below) 🗆 No	
Based upon the above response	es, the subject is: 🗗 Qu	ialified □ Not (Qualified to contin	ue on the study.
Reasons for disqualificati	on:			
	•			
TO BE CO	MPLETED IF SUBJ	ECT HAS AN IN	TERCURRENT II	LINESS
Date of Onset:	Date Reported	•	Date Resolve	d:
Describe condition:			•	
☐ Medicatio	ntinued on study	Withdrawn from	the study	nsulted physician
Additional Comments:				
	CON	COMITANT ME	,	
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm/dd/yy	Indication (Reason for Taking)
		1 1	1 1	
		1 1	/ /	
		1 1	1 1	
Comments:				3 / 63

mm

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HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07/23/03 mm dd yy	J/L/C F. M L	Permanent #:	03-122085-106

		BAS	ELINE				
LEFT	HAND DILUTIO	NS	RIGHT HAND DILUTIONS				
10-4	10 ⁻⁵	10-6	10-4	10-5	10-6		
TNTC	138	14	TNIC	167	22		
TNTC	156	13	TATE	190	19		
CFU/mL/.5x18	Counted by:	M 17/25/03	CFU/mL /. 8×/0	Counted by : _	080/7.25.03		

LEFT HAND			W.	RIGHT HAND			
10-1	10-2	10-3	10-4	10 ⁻¹	10-2	10-3	10-4
TNTC	TNTC	198	29	TNTC	TNTC	101	7
TUTC	TNTC	179	19	TNTC	TNTC	129	16
TNTC				TUTC			
CFU/mL 2.1 X 105	. Counte	ed by :	Of 17.25.03.	CFU/mL /.2 × 105	Counted by:	gen 1	7.25.03

				RIGHT HAND		
10-3	10 ⁻⁴	10-1	10-2	10-3	10-4	
168	- 14	TNTC	TNTC	72	. 13	
. 180	- 24	TNTC	TNTC	97	12	
		TNIC			W	
nted by :	17.25.03	CFU/mL 8.7 x 108	Counted by:	_ an 1	7.25.03	
	168	168 14	168 14 TNTC 180 24 TNTC TNTC unted by: Of 17.25.03 CFU/mL 8.7 X ID 5	TATE TATE 168 - 14 TATE TATE TATE	168 14 TNTC TNTC 72 180 24 TNTC TNTC 97 TNTC	

@ 74 7-26.03

Calculations by: 76 17-26-63 Raw data reviewed by 216 1 6.1.03 Calculations Verified by: JNB 107-29-03	
Calculations Verified by:	•
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.	
Underlined values are used for calculation of CFU/mL	
TNTC – Too Numerous To Count	

Investigator's Signature:

| Date: 9 | 1 | 03 | mm | dd | yy

Subject Initials <u>V2C</u>	Subject #	Study No. Page No.	03-122085-106 TV - 456
	ADVEDCE EXPENTS		

ADVERSE EVENTS

Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Relation—Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Relation—Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Relation—Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Relation—Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Ship Signature/Date		· · · · · · · · · · · · · · · · · · ·	•								
Entry Comment/Note: 7-2703 9/03 N 1 1 44 By Septity Comment/Note: 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	∽Syr	nptom / Event	Onset Date	End Date		Severity		Outcome			
Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Relation—Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Relation—Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Outcome Relation—Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Outcome Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Signature/Date Symptom / Event Onset Date End Date SAE' Severity Action Taken Outcome Signature/Date	Pay	bules	7-27-03	9/1/03	N	1		1	44	1 Jen	
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Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Relation-Signature/Date Entry Comment/Note: Initials Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Relation-Signature/Date Entry Comment/Note: Initials	280	3 Three.	red &	bake	ule	0	n iln	the s	west	sto	2/05
Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Relation- Signature/Date Entry Date Comment/Note: Initials Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Relation- Signature/Date Entry Comment/Note: Initials		and of	bream	me	1,						& X J
Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Relation-Signature/Date Entry Date Comment/Note: Initials Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Relation-Signature/Date Entry Comment/Note: Initials	1/03	Hands & u	wrist is	lean.	- <u>n</u> u	o me	dicat	TONS	USEL	2	an
Symptom / Event Onset Date End Date Y/N Seventy Taken Outcome ship Signature/Date Entry Date Comment/Note: Initials Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Ship Signature/Date Entry Comment/Note: Severity Action Taken Outcome Ship Signature/Date									•		0
Entry Date Comment/Note: Initials Symptom / Event Onset Date End Date SAE1 Severity Action Taken Outcome Relation-Signature/Date Entry Comment/Note: Signature/Date			Onset Date	End Date	SAE	Severity		Outcome			
Symptom / Event Onset Date End Date SAE ¹ Severity Action Taken Outcome Ship Signature/Date Entry Comment/Note:	Sy	mptom / Event	·		Y/N		Taken	,	ship	Signati	ure/Date
Symptom / Event Onset Date End Date SAE¹ Severity Action Taken Outcome Ship Investigator Signature/Date		Comment/Note:			<u> </u>				<u> </u>		Initials
Symptom / Event Oriset Date End Date Y/N Severity Taken Outcome ship Signature/Date	Duio						T1 - 111 - 11 - 11 - 11 - 11 - 11 - 11				
Symptom / Event Oriset Date End Date Y/N Severity Taken Outcome ship Signature/Date								······································			
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	S	ymptom / Event	Onset Date	End Date		Severity		Outcome			ture/Date
Date Online Initials		Comment/Note:				<u>, </u>			•		1
	Date	Comment vivole.				- 					Initials
										·	
								· · · · · · · · · · · · · · · · · · ·			
				*						·-	
						•					
Note: Severity, Relationship and Outcome MUST be determined by principal investigator. Severity: 1=Mild 2=Moderate 3=Severe	Note:	Severity, Relatio	nship and	Outcome	MU derate	ST be d	etermine	d by prin	cipal inv	estigato	or.

Relationship:

1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken:

1=None

2=Rx Therapy

3=Discontinued Study

4=Other (specify)

Outcome:

1=Resolved w/o sequelae

2=Resolved w/ sequelae 3=Ongoing (describe)

4=Death

¹Serious Adverse Event/Experience

HTR Study No.: 03-122085-

FOLLOW-UP VISIT

Page No.: 11 - 457 Subject Screen #: Visit Code Date Subject Initials Study# Permanent #: Follow-up 03-122085-106 Visit mm dd M

	Date Subject Entered the Study: 07/15/03	Follow-Up V	~
	mm dd yy	mm do	і уу
	Does the subject's hands have the presence of pimples, blisters, that may be indicative of a skin infection? Y YES INO If yes, complete below:	or raised itching bumps surrounded b	y erythema and/or edema
	Clinical Observations: (Include date of onset and descriptions/s Three negl papells a Ousef on 7-27-03	everity/locations, etc.) N Wrests and	foreams
	Comments:		
	Has the subject had any health related issues since the treatment	procedure?	
	☐ YES NO If yes, complete below		
	Comments:		
L			
-			
	Medical Consultant's Signature:	n n	Date 7 128103 am dd yy

dd

 $\mathbf{m}\mathbf{m}$

Data Collection Form 1

Page No.: IV -

DEMOGRAPHICS/DERMATOLOGICAL/MEDICAL HISTORY FORM

Visit Code	Date	Subject Initials	1 .	en #:	Study#	
Subject Qualification	07/15/03 mm dd yy	BIAIG FM L		44	03-122085-106	
			 		;	
☐ Male	Female.		A	.ge:	Years	
ubject have any of	the following at the	treatment sites?				
TATOLOGIC DIS	ORDER			No	Yes	Don't
						Know
				<i>V/</i>		
					,	
	eace checify			- 1/		
	ease specify.			1/		
Subject have any of	the following (pres	ent and past)?				
ER MEDICAL IN	FORMATION			No	Yes	Don't Know
Allergies.? Please	specify. Phylica	nmental		_		
Hepatitis?		· .		1		
Heart and Vascular	Disease?			V		
Liver Disease ?		· · · · · · · · · · · · · · · · · · ·		11/		
Kidney Disease?				V		
				1//		
	olled? Diet[] C	ral[] Insulin[]		V	,	
	ase (Lunus erythema	tosus, thyroiditis, A	TDS, etc.) ?			
				1	$\overline{\mathcal{A}}$	
		e specify:		1		
			,	1		<u>L</u>
				No	Ves	Don't
				 	4	Know
		ion Daviga 9		\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \	<u> </u>	
		ion Drugs :		+V	<u> </u>	
	-			+V	/	
				+V	/	
Other?				$\perp \qquad		1
nts:		T/O 115		N	NG 1 6 4	
the above medical h	ustory, the subject is	: LYOualifie	ea or 🗆	Not qua	infied for the s	mav.
	Subject Qualification Male Ibject have any of a MATOLOGIC DIS Psoriasis? Eczema? Skin Cancer? Skin Allergies? Please Hives? Subject have any of ER MEDICAL IN Allergies.? Please Hepatitis? Heart and Vascular Liver Disease? Kidney Disease? Tuberculosis? Diabetes? Contractory Auto-immune dise Organ transplant? Any other condition oject taking any mee DICATION Antibiotics, oral oral control Cortisone, Steroid Heart Medication Insulin? Other?	Subject Qualification Male Female Ibject have any of the following at the MATOLOGIC DISORDER Psoriasis? Eczema? Skin Cancer? Skin Allergies? Please specify: Hives? Subject have any of the following (present in the property of the following (present in the followi	Subject Qualification OT/15/03 EMM L Diject have any of the following at the treatment sites? MATOLOGIC DISORDER Psoriasis? Eczema? Skin Cancer? Skin Allergies? Please specify: Hives? Subject have any of the following (present and past)? ER MEDICAL INFORMATION Allergies.? Please specify. Environmental Hepatitis? Heart and Vascular Disease? Liver Disease? Kidney Disease? Tuberculosis? Diabetes? Controlled? Diet[] Oral[] Insulin[] Cancer? Auto-immune disease (Lupus erythematosus, thyroiditis, A Organ transplant? Any other condition not listed? Please specify: Oject taking any medication? If yes, please specify below: DICATION Antibiotics, oral or systemic? Cortisone, Steroids, ACTH, Anti-reaction Drugs? Heart Medication? Insulin? Other?	Subject Qualification Subject Qualification O7/15/03 B/A/G Permanent #	Subject Qualification Male Female Age: 2	Subject Qualification Subject Qualification O7/15/03 B/A/C Permanent #: O3-122085-106

Data Collection Form 2 INCLUSION / EXCLUSION FORM

HTR Study No.: 03-122085-Page No.: TV - 2

Visit Code	Date	Subject Initials	Subject Screen #: 132	Study #	
Subject Qualification	07/15/03 mm dd yy	BIAIG f m 1	Permanent#: 44	03-122085-106	

			INCLUSION CRITERIA
Ch	eck one		
YES	/ NO)	Subject:
V	/		1. Is 18 through 65 years?
V			2. Has signed informed consent?
V			3. Is healthy as evidenced by responses on DCF 1?
V	1		4. Has hands and wrists that are free of dermatoses, cuts, lesions, and other skin disorders?
1/			5. Has fingernails that extend no longer than approximately one (1) mm past the nail bed?
V			6. Is willing to refrain from using antimicrobial soaps (liquids and/or bars) for bathing, showering, and handwashing during the entire study?
1			7. Is willing to refrain from using anti-dandruff shampoo during the entire study?
			8. Is willing to refrain from using body lotions, medicated/antibacterial lotions, creams, oils, dishwashing liquids, tales and other deodorant/antiperspirant products during the entire study, unless prescribed by a physician for an intercurrent illness?
V	1		9. Is willing to refrain from using topical steroids during the entire study, unless prescribed by a physician for an intercurrent illness?
V	1		10. Is willing to refrain from using topical or systemic antibiotic medication during the entire study, unless prescribed by a physician for an intercurrent illness?
			11. Is willing to comply with all study protocol requirements?
			EXCLUSION CRITERIA
C	heck one	· ·	·
) YES	NO /	N/A	Subject:
	V	/	1. Is currently participating in another clinical study at this or any other facility?
		/,	2. Has participated in any type of hand or arm wash study within the past 7 days?
		7	3. Has cuts, lesions, or other skin disorders on their hands or wrists?
	V	7	4. Has artificial nails or nail tips?
	V		5. Has soap, detergent, antibiotic, Polysporin® and/or perfume allergies?
			6. Has eczema or psoriasis on their hands or wrists?
Female	Female	Male	7. Is currently pregnant? ☐ Yes ☑ No Of child-bearing potential: ☑ Yes ☐ No
	V	_	Surgically Sterile, year Post-menopausal, year If of child bearing potential - β-HCG Test Results: In negative positive 7123103 0910
			8. Is currently lactating?
	V		
			9. Has been medically diagnosed as having a medical condition such as: diabetes, hepatitis, an organ transplant, an immunologic disease such as AIDS (or HIV positive), Lupus erythematosus, thyroiditis or rheumatoid arthritis?
		/	10. Has another medical condition which in the opinion of the Investigator would preclude participation?
	1/		11. Has any responsibility for care of children under age 3, or has responsibilities for diapering, care of wounds, intravenous management or other bed-ridden related care roles.
	V		12. Has a known sensitivity to isopropyl alcohol or the ingredients in antibacterial soaps?
		1.	the state of the s
Based		mattolog W Qua	ric evaluation and the information contained in Data Collection Forms 1 and 2, the subject is: lified Not Qualified for participation in this study.
Reaso	ons for disc		TND ATLEAS
-	gator's Sigr	· · · · · · ·	Date: 08 110 103 mm dd yy
	· ·		

HTR Study No.: 03-122085-10 Page No.: W-

Data Collection Form 3

INTERCURRENT ILLNESS / CONCOMITANT MEDICATION FORM

Visit Code	Date	Subject Initials	Subject Screen #:	Study #
Test Period	07 /23 /03 mm dd yy	<u>B/A/G</u> F M L	Permanent#: 44	03-122085-106

I. Is skin on subject's hands as If no, please indicate con				
II. Has subject used non-antib	-			es ONo
III. Has subject been ill since the		_	,	
IV. Has subject used any new of		_	•	
Based upon the above respon Reasons for disqualifica			_	•
то ве с	OMPLETED IF SUBJ	ECT HAS AN I	TERCURRENT I	LLNESS .
Date of Onset:	Date Reported	•	Date Resolve	ed:
Describe condition:			•	•
Was reaction related to treatment Action Taken: □None □ C □ Medicati Additional Comments:	continued on study	Withdrawn from	the study	nsulted physician in)
	CON	COMITANT ME	DICATION	
Medication (Oral or Systemic)	Total Daily Dose	Start Date mm / dd / yy	Stop Date mm / dd / yy	Indication (Reason for Taking)
		1 1	/ /	
		1 1	/ /	·
•		1 1	1 1	
Comments:				
Interviewer's Signature: 4	<i>l</i> 11 -	, I	Date: 07 / 2	23 / 03

HEALTH CARE PERSONNEL HANDWASH BACTERIAL COUNTS

CFU/mL of Sampling Solution

Test Date	Subject Initials	Subject Screen #	Study#
07/23/03 mm dd yy	B/A/G F. M. L	Permanent #:	03-122085-106

		BAS	ELINE	***************************************			
LEF	I HAND DILUT	ONS	RIGHT HAND DILUTIONS				
10-4	10-5	10 ⁻⁶	10-4	10-5	10-6		
TATE	116	11	nrc	160	19		
THE	15,0	15	MI	128	11		
CFU/mL/ <u>.3</u> 8/	O Counted by: <u>C</u>	10 17.25.03	CFU/mL /.47/	Counted by:	KB 17.25.		

LEFT HAND		WASH 1					
10-1	10-2	10 ⁻³	10-4	10 ⁻¹	10-2	10-3	1
ThTZ	TUTE	138_	9	THE	THE	79_	a
Th 72	TUTC	120	- 17	THIT	THITC	102	9
THI				Th TC.			
CFU/mL /.3 x10 5	Count	ed by : _ <i>QU</i>	17.25.03	CFU/mL 9.0 X 10 4	Counted by	: als	/ 7. 2 e

LEFT HAND		WASH 11					
10-1	10 ⁻²	10 ⁻³	10-4	10 ⁻¹	10-2	10 ⁻³]
TUTE	TUTE	77	- 7	TUTC	TATC	70	3
TUTC	TUR	84	- 9	TRTC	THR	62	
THE				ThTL	/	1	
CFU/mL 8.0 × 104	Counte	d by : <i>Alb</i>	17.25.03	CFU/mL6.8×104	_ Counted by	: arb 1	7.0

Calculations by: 70 /786-03 Raw data reviewed by JNB Calculations Verified by: JNB /07.29.03	108.01.03
Calculations Verified by:	
*10-1 dilution is the sum of 1.0 mL spread across 3 plates.	
Underlined values are used for calculation of CFU/mL	
TNTC – Too Numerous To Count	

Investigator's Signature:	15 11	Date:	9	110	103	
	10 Mul /		mm	đđ	уу	1

Subject Initials	_BAG	Subject #_	44	

Study No. Page No.

ADVERSE EVENTS

Sy	/mptom / Event	Onset Date	End Date	SAE ¹ Y/N	Severity	Action Taken	Outcome	Relation- ship	investi Signatui	gat re/[
red b	rumos wlites	7/24/03	8/15/03	N		411)		4/2)	De Jos	1
Entry Date	Comment/Note: 1) [sel Hon F	x corti	sen	Dom	-20u	ett	logo	repris	ن In پرچه
25/03	red bun	ros in	ith	Ż	chin	g on	bet	8 S	21-95	.
15/03	Cortisono	Crear	n 1	se	d	2 tin	us)	ow	• .	
	7/28/03.	Hano	ls e	"El	ar	##. d				
				··						
s	ymptom / Event	Onset Date	End Date	SAE ¹	Severity	Action Taken	Outcome	Relation- ship	Invest Signatu	
	o above.	don a	rtes	8)	15/0	3 08	X	Still	Signatu	II e
Enter	Comment/Note:					T.	1	1		In
	Has used	'cortiso	no c	200	m.					CO.
	7			<i></i>	<u> </u>				7-	28
								· · · · · · · · · · · · · · · · · · ·		
		•						ı		
		Onset Date	Find Date	SAE ¹	0	Action		Relation-	Inves	tias
	Symptom / Event	Oliset Date	End Date	Y/N	Severity	Taken	Outcome	ship	Signati	
Entry Date	Comment/Note:							<u> </u>		l:
Date										
					·		,			
					, , , , , , , , , , , , , , , , , , , 			***************************************		-
			•				V-V			
L					•			 		

Note: Severity, Relationship and Outcome MUST be determined by principal investigator.

Severity:

1=Mild

2=Moderate

3=Severe

Relationship:

1=Definite

2=Probable

3=Possible

4=Unrelated

Action Taken:

1=None

2=Rx Therapy

3=Discontinued Study

4=Other (spe

Outcome:

1=Resolved w/o sequelae

2=Resolved w/ sequelae 3=Ongoing (describe)

4=Death

¹Serious Adverse Event/Experience